DEC 23 2004

10. 510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name
Proprietary Device Name: Infinia LightSpeed

Establishment Name and Registration Number of Submitter

Name:	GE MEDICAL SYSTEMS F.I, HAIFA
Registration Number:	9613299
Corresponding Official:	Laurence Bigio GE MEDICAL SYSTEMS F.I, HAIFA P.O. Box 170 Tirat Hacarmel 30200, ISRAEL

Device Classification

Classification Code:	90 KPS & 90 JAK
Panel Identification:	Radiology
Classification Name:	System Emission Computed Tomography (per 21CFR 892.1200) System Computed Tomography (per 21CFR 892.1750)
Common Name:	Single Photon Emission Computed Tomography Computed Tomography X-Ray
Classification Class:	Class II Product

Performance standards:

- Code of Federal Regulations Title 21 Subchapter J- Radiological Health - 21CFR1020.30, 21CFR 1020.33.
- NEMA NU 1-2001.
- IEC60601-1 and associated collateral and particular standards.

Reason for 510(k) Submission
Modifications of legally marketed devices.

Identification of Legally Marketed Equivalent Devices

GE Quasar Nuclear Medicine System ("Infinia")	K022960
"LightSpeed" 5.0 Computed Tomography System	K030420
Hawkeye Option for Dual Head Variable Angle Gamma Camera	K991841

Device Description
The "Infinia LightSpeed" system is a combination of the Infinia NM Scanner (K022960 & K991841) and the "LightSpeed" 5 CT Scanner (K030420). In addition to providing CT and NM standalone capabilities, it uses the CT images to correct for non-uniform attenuation of the NM images and to facilitate localization of the emission activity in the patient anatomy.

Description of Change or Modification

The Infinia Scanner (K022960) has been modified to accommodate for the CT subsystem, by including a means to align the gantries, a common table and additional software for use of CT for purposes of attenuation correction.

Intended Use of Device

The intended use of the "Infinia LightSpeed" system is to perform:

- General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in oncology, cardiology, neurology and other clinical diagnostic imaging applications.
- General Head & Body computed tomography (CT) applications.
- Combined, hybrid SPECT & CT protocols, for CT-based SPECT attenuation correction imaging as well as functional and anatomical mapping imaging (registration and fusion).

Summary of Studies

Phantom data shows that SPECT/CT attenuation-corrected images are more uniform than NM images without attenuation correction. The images also demonstrate the localization capabilities of the SPECT/CT.

Conclusion

In the opinion of GE MEDICAL SYSTEMS F.I, HAIFA the "Infinia LightSpeed" is substantially equivalent in terms of safety and effectiveness to the legally marketed Infinia (K022960) equipped with the Hawkeye option (K991841) and to the legally marketed LightSpeed 5.0 (K030420), based upon similar intended use and system performances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 2004

GE Medical Systems
F.I. HAIFA (9613299)
% Mr. Alex Grob
Senior Project Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

Re: K043381
Trade/Device Name: Infinia LightSpeed
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: December 6, 2004
Received: December 9, 2004

Dear Mr. Grob:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K043381

Device Name: Infinia LightSpeed

Indications for Use

The intended use of the "Infinia LightSpeed" system is to perform:

- General Nuclear Medicine imaging procedures for detection of radioisotope tracer uptake in the patient body, using a variety of scanning modes supported by various acquisition types and optional imaging features designed to enhance image quality in oncology, cardiology, neurology and other clinical diagnostic imaging applications.
- General Head & Body computed tomography (CT) applications.
- Combined, hybrid SPECT & CT protocols, for CT-based SPECT attenuation correction imaging as well as functional and anatomical mapping imaging (registration and fusion).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David A. Ayres

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043381